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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; and THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

vs.

JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, and JOHNSON & JOHNSON,

Defendants.

Case No.: 3:17-cv-07250-JST

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT

Judge: Hon. Jon S. Tigar
Date: May 16, 2019
Time: 2:00 PM
Place: Courtroom 9, 19th Floor, Phillip Burton Federal Building

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INTRODUCTION

Relator's Opposition ("Opp.") confirms that his theory of False Claims Act ("FCA") liability is as sweeping as it is novel. His attempt to connect purportedly false statements to a claim for payment to the United States traverses at least three distinct and complex regulatory schemes, and asks the Court to indulge unsubstantiated and unwarranted inferences and assumptions. Relator pleads no facts, for example, to satisfy the required elements for legal falsity, including no facts to support the claim of inequitable conduct before the United States Patent and Trademark Office ("USPTO"), on which his whole Complaint (ECF No. 7) ("Complaint" or "AC") hinges. Nor does he plead facts to support the assertion that officials responsible for reimbursement payments, or for approving drugs for the Federal Supply Schedule ("FSS"), would even take into consideration representations made to the USPTO, much less that those decision-makers would be materially influenced by such representations. The Opposition leaves all of these points untouched.

The Court need not even reach the substance of Relator's allegations, however, because the Complaint fails at the threshold under the public disclosure bar. Setting aside Relator's misguided impression that the FCA's 2010 amendments paved the way for "outsiders" such as himself, the Opposition cannot obscure the basic facts that the claims were cribbed from the public domain, that Relator is not an original source, and that the FCA forbids such copycat pleadings. The Court should dismiss the Complaint with prejudice.

ARGUMENT

I. THE PUBLIC DISCLOSURE BAR PRECLUDES RELATOR'S CLAIMS

Relator's Opposition ends where this Court should begin—with the FCA's public disclosure bar. Defendants' Motion to Dismiss ("Motion" or "Mot.") explained that, (A) substantially the same allegations or transactions were publicly disclosed, and (B) Relator is not an "original source." The Opposition offers no good response to these fatal defects and, in many respects, barely even tries. The Complaint should be dismissed on this basis alone.[1]

[1] Relator misinterprets the 2010 amendments when he suggests that arguments under the public disclosure bar are "not proper under Rule 12(b)." Opp. at 20, n.12. The statute still says that "the court *shall* dismiss an action or claim" when the public disclosure bar applies, 31 U.S.C. § 3730(e)(4)(A) (emphasis added), and it "is appropriately resolved on a motion to dismiss," *U.S. ex rel. Ambrosecchia v. Paddock Labs., LLC*, 855 F.3d 949, 953 (8th Cir. 2017).

A. Relator's Allegations Were Previously Disclosed Through Enumerated Sources.

The public disclosure bar precludes lawsuits premised on "substantially the same allegations *or transactions*" previously disclosed, 31 U.S.C. § 3730(e)(4)(A) (emphasis added), and the disclosure "need not contain an explicit 'allegation' of fraud, so long as the *material elements* of the allegedly fraudulent 'transaction' are disclosed in the public domain." *U.S. ex rel. Mateski v. Raytheon Co.*, 816 F.3d 565, 571 (9th Cir. 2016) (emphasis added) (quoting *U.S. ex rel. Found. Aiding the Elderly v. Horizon W., Inc.*, 265 F.3d 1011, 1014 (9th Cir. 2001)). Applying the plain text of the statute, the Ninth Circuit and this Court apply the "X+Y=Z" framework to evaluate application of the bar: so long as either (1) the "Z" (the alleged fraud) is itself disclosed, or (2) the "X" and the "Y" (the misrepresented and true facts) are disclosed such that the "Z" can be inferred, the bar applies. Mot. at 5–6 (citing *Amphastar Pharm. Inc. v. Aventis Pharma SA*, 856 F.3d 696, 703 (9th Cir. 2017)).[2] Both are true here, and Relator's only genuine dispute is with *how* the content was disclosed—not whether it *was*, in fact, disclosed.

1. Relator Ignores The Controlling Legal Framework For Determining Whether There Was A Public Disclosure.

Relator's Opposition fails to engage with, or indeed even to discuss, the X+Y=Z framework. Relator effectively ignores half of the equation (the "X" and the "Y"), while also failing to appreciate that even the allegations of fraud (the "Z") were publicly disclosed. Either half of the equation is independently sufficient.

With respect to the "X+Y," the Motion showed how both the misrepresented state of facts and the true state of facts were publicly known.[3] Relator all but concedes that the "Y" has been

[2] Relator complains that *Amphastar* is a pre-amendment case. Opp. at 20–21. But, Relator identifies nothing in the 2010 amendments that invalidated this approach, nor has the Ninth Circuit or any other court repudiated the Circuit's approach. To the contrary, the "X+Y=Z" framework continues to be the governing approach. *See, e.g.*, *U.S. ex rel. Fryberger v. Kiewit Pac. Co.*, 41 F. Supp. 3d 796, 804 (N.D. Cal. 2014).

[3] In resolving Rule 12(b)(6) motions, courts may take judicial notice as appropriate. *See, e.g.*, *U.S. ex rel. Hong v. Newport Sensors, Inc.*, 728 F. App'x 660, 661 (9th Cir. 2018). Relator "does not oppose" Defendants' Request for Judicial Notice ("RJN") of exhibits submitted to the Court on February 25, 2019, yet in his Response to Defendants' Request for Judicial Notice, nonetheless offers substantive argument. The Court should ignore these improperly placed contentions. The exhibits requested to be noticed are clear as to the facts disclosed and those facts are not subject to varying interpretations nor are they internally consistent. The exhibits are therefore appropriately noticed for

disclosed. *See* Opp. at 24. And the "X,"—*i.e.*, the June 4, 2013 patent application submission ("June 4 submission") in which Defendants allegedly made the misleading omissions—was also publicly disclosed to the USPTO and to the public during the patent prosecution itself. *See infra* at 5–7. Under this formula, more than sufficient information was publicly disclosed such that "readers or listeners may infer Z," *i.e.*, the allegation that certain facts existed which should (allegedly) have been disclosed by Defendants in the June 4 submission.[4] *Mateski*, 816 F.3d at 571. That is all that is required, and the Court may end its analysis there.

Even considering the analysis on Relator's own terms, the "X+Y" is still readily satisfied. Relator invites the Court to focus on what he calls the "most important allegation" and "the very essence of the fraud"—by which he means the supposed omission that Xtandi was not yet approved for the chemo-naïve market. Opp. at 22–23. But, that alleged "misrepresented state of facts" (the "X") is self-evident from the June 4 submission itself. *See* RJN, Ex. C. And the alleged true state of facts (the "Y")—*i.e.*, that Xtandi had not received FDA approval for the chemo-naïve market—was also publicly available through a variety of sources, including an FDA press release, *id.* at 41–42, and news articles detailing FDA approval of Xtandi only for prostate cancer patients previously treated with docetaxel, RJN Ex. U. Again, that was sufficient.

As for the "Z," Relator's Opposition generally but erroneously proceeds as if this must *also* be publicly disclosed. The Opposition argues, for example, that even if the "*real* reasons for Zytiga's commercial success (unrelated to the claimed invention in the '438 Patent) were publicly disclosed, this does not mean that the essential elements of Relator's *fraud allegations* were publicly disclosed." Opp. at 24. Relator further alleges "that Defendants *should* have but *did not* disclose such reasons for Zytiga's apparent commercial success to the USPTO," but "*that fact* was not disclosed in any

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the purpose of establishing facts within the public domain at the time of disclosure. These publicly available documents are representative and emblematic of the prior public disclosure of the transactions and allegations in Relator's Complaint, but are in no way an exhaustive set of sources. Defendants reserve their rights to request the Court take judicial notice of additional exhibits, as needed.

[4] Relator briefly asserts that the publication on a Department of Veterans Affairs ("VA") website of the existence of Defendants' FSS contract and the price at which Zytiga is sold under that FSS contract lacks the "disclosure of specific, granular details sufficient to alert the government of fraud." Opp. at 24–25. But, the relevant fraud rests on the alleged misrepresentations made to the USPTO, not the VA, and Defendants' Motion never argued that FSS disclosures mattered for the public disclosure analysis. Mot. at 5–12.

document upon which Defendants rely." *Id.* (last emphasis added). But these "facts" are not fact at all—it is the allegation itself, the "Z," and does not need to be independently disclosed. *Amphastar*, 856 F.3d at 704. Worse for Relator still, the "Z" in this case *was* disclosed, because it was expressly referenced in the Amerigen *inter partes* review ("IPR") petition. *See* Mot. at 7–9 (citing and quoting from RJN Ex. D). In short, the "X," the "Y," *and* the "Z" of the Complaint's core allegations of fraud were all publicly disclosed.

2. Relator's Allegations Were Disclosed In A Statutorily Required Manner.

Relator's remaining arguments do not concern the substance of the public disclosures but contend only that they did not take the correct form. Wrong again. The public disclosure bar is broad, *see Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 408 (2011), and includes both of the sources—namely, the IPRs and patent prosecution—from which Relator harvested his Complaint.

First, Relator argues that information in the IPR petitions was not publicly disclosed in "one of the specified ways." Opp. at 21. That is incorrect. Relator argues that an IPR petition is not a qualifying disclosure because the government is not a party to IPR proceedings as required under 31 U.S.C. § 3730(e)(4)(A)(i). *Id.* That is true, and irrelevant. Defendants nowhere argued that the IPR petitions *themselves* satisfied the bar but, rather, argued that the subsequent public disclosure of the IPR petitions and docket information through other qualifying channels, such as the Patent Trial & Appeal Board's ("PTAB") website, news articles, and SEC filings,[5] qualify as publicly available "news media" under § 3730(e)(4)(iii). Mot. at 7. That is why, for example, another California court recognized that "filings in litigation to which the Government was not a party are not identified in Section 3730(e)(4)(A)," but such filings are nonetheless "properly treated as [] public disclosure[s]" when they are "identified through links that were part of the article in *Law360*." *United States v. Kimberly-Clark Corp.*, No. LA CV 14-08313 JAK, 2017 WL 10439028, at *6 (C.D. Cal. July 14, 2017); *see also U.S. ex rel. Proctor v. Safeway, Inc.*, No. 11-cv-3406, 2016 WL 7017231, at *12 (C.D. Ill. Dec. 1, 2016) (article identifying lawsuit is a public disclosure).

Relator also contends that the IPR petitions could not have disclosed his allegations of fraud

[5] In addition to being publicly available online, SEC filings are "a type of federal report," prepared for the federal government pursuant to federal regulations. *U.S. ex rel. Calilung v. Ormat Indus., Ltd.*, No. 3:14-CV-00325-RCJ-VPC, 2015 WL 1321029, at *16 (D. Nev. Mar. 24, 2015).

because "inequitable conduct" claims cannot be raised in IPR proceedings. Opp. at 22. This too is a straw man argument. The FCA does not require that a claim of fraud be disclosed in a proceeding or forum that could entertain the merits of a fraud claim, only that the claim or its essential elements be disclosed. Indeed, such a rule would be irreconcilable with the Ninth Circuit's instruction that a disclosure "need not contain an explicit 'allegation' of fraud." *Mateski*, 816 F.3d at 571 (quoting *U.S. ex rel. Found. Aiding the Elderly*, 265 F.3d at 1014). Relator's allegations simply parrot contentions first articulated in the IPRs, and that is what counts.[6] *See* Mot. at 7–9. That the PTAB cannot "invalidate a patent based on fraud or inequitable conduct," Opp. at 22, makes no difference.

Second, Relator contends that a patent prosecution is not a public disclosure under the FCA. *Id.* at 22–24. This is wrong on several levels. In a patent prosecution, applicants submit information directly *to* the government itself, unmediated by any third party or intervening source, which by definition means that the government had notice of the information. *See Mateski*, 816 F.3d at 574 (emphasizing the notice purpose of public disclosure bar). Regardless, the June 4 submission was publicly available through at least two additional forms of disclosures. For one, documents submitted as part of a patent prosecution are disclosed through a "federal hearing," § 3730(e)(4)(A)(ii), because a "hearing" includes "any type of [federal] 'legal proceeding,'" which a patent prosecution clearly is, *U.S. ex rel. Alexander v. Dyncorp, Inc.*, 924 F. Supp. 292, 299 (D.D.C. 1996). Another is the *Public* Patent Application Information Retrieval ("PAIR"), a federal database that is available to the public free of charge through the USPTO's website, without any form of sign-up or log-in.[7] PAIR compiles patent prosecution histories as well as various patent reports and applications and is therefore a "federal report" within the meaning of the public disclosure bar, because it "gives information or a notification," *Schindler Elevator Corp.*, 563 U.S. at 407–08 (quoting *Webster's Third New International Dictionary* 1925 (1986)), or is "[a]n official or formal statement of facts or proceedings," *id.* (alteration in original) (quoting *Black's Law Dictionary* 1300 (6th ed. 1990)). PAIR

[6] Relator mischaracterizes Defendants' discussions of the IPR petitions as conceding the alleged failure to disclose that Xtandi had not obtained FDA approval. *See* Opp. at 22. Defendants have not and do not concede this. All that Defendants' Motion did was note that the FDA press release for Xtandi was included in the patent prosecution submission and that Relator merely concocted a theory of fraud based on publicly available information.

[7] In this way, PAIR is distinct from PACER, Opp. at 23, which requires a member of the public to obtain a username and pay fees per usage.

compiles and synthesizes information about patent histories for any member of the public, and courts have treated analogous databases as public disclosures. *See, e.g.*, *U.S. ex rel. Rosner v. WB/Stellar IP Owner, L.L.C.*, 739 F. Supp. 2d 396 (S.D.N.Y. 2010) (noting a publicly searchable database on city agency's website was an administrative report subject to public disclosure bar). The June 4 submission was a public disclosure within the meaning of Section 3730.

B. Relator Has Not Sufficiently Pled Facts To Indicate He Is An Original Source.

Relator concludes by defending his naked allegation that he is an "original source," claiming that he is the "only source" of his allegations because he brings "particular knowledge and expertise" as a patent lawyer, and because it "took a great deal of technical, scientific, and legal expertise" to identify the alleged fraud. Opp. at 25. But Relator does not plead any facts identifying his methodology or a single source of non-public information. *Id.* at 7. The fact therefore remains that the Complaint "simply parrots the standard for determining an original source without providing any factual basis for the claim," *United States v. Kimberly-Clark Corp.*, No. LA CV14-08313 JAK, 2017 WL 10439690, at *8 (C.D. Cal. Nov. 30, 2017), and Relator's conclusory assertions to the contrary do not change that bottom line. This is nothing more than "'opportunistic' litigation that the public disclosure bar is designed to discourage." *Schindler Elevator Corp.*, 563 U.S. at 413.

II. RELATOR FAILED TO ALLEGE A VIOLATION OF THE FALSE CLAIMS ACT.

Relator's Opposition presents a patchwork of arguments and authority attempting to satisfy the FCA's exacting requirements. This crazy quilt does not hang together. Indeed, despite Relator's best efforts to square his claims with *Universal Health Services Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016), and *U.S. ex rel. Campie v. Gilead Sciences*, 862 F.3d 890 (9th Cir. 2017), those cases highlight Relator's shortcomings and underscore his improper attempt to turn the FCA into an "all-purpose antifraud statute." *Escobar*, 136 S. Ct. at 2003.

A. Relator Has Not Pled The Submission Of A Claim.

As noted previously, the Complaint omits the "who, what, when, where, and how" of the purported false claims, and in particular fails to allege the "particular details of a scheme to submit false claims." Mot. at 14 (citing *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 998–99 (9th Cir. 2010)). Moreover, Relator was not excused from these requirements by his "outsider" status, nor may he rely

on the pleading lifeline of "information and belief." *Id.* Relator attempts to distinguish *Ebeid* on the grounds that the relator there did not plead "any" facts, but, even if true, that does not bless Relator's failure here to plead *sufficient* Rule 9(b)-compliant facts. *See* Opp. at 14. Instead, Relator summarily asserts that he pled the "particular details of a scheme" that reliably lead to a strong inference that false claims were submitted in alleging that in 2015 and a small portion of 2017 Medicare and Medicaid reimbursed over 80,000 prescriptions for Zytiga totaling over $650 million, all of which were false. *Id.* at 14 (citing AC ¶¶ 11–13). But, as if to demonstrate Defendants' point, Relator does not dispute that his estimation of the number of prescriptions written for Zytiga in 2017 is wholly unsupported, *see* Mot. at 14, and glosses over that fact by referencing back to the number of prescriptions submitted in 2015—well before the time period at issue here. That is neither particularized nor reliable, and the lack of detail surrounding the claims at issue preclude Relator from connecting the allegations of fraud to the actual claims for payment. *See id.* at 15.

B. Relator Has Not Pled A "False" Claim.

Picking up where the Complaint left off, Relator's Opposition variously argues that Defendants made "express *and* implied representations," Opp. at 9 (emphasis in original), "false statements," *id.* at 14, "false [and] misleading representations," *id.* at 15, and "certifications," *id.*, or that Defendants otherwise "incorporate[d] an unlawfully inflated price" in a claim for payment, *id.*[8] Relator's inability to articulate a cogent theory of falsity exposes the lack of nexus between the alleged regulatory violation and the submission of a false claim and reveals the frailty of the claim.

1. Relator Fails To Plead A False Statement Connected To A Claim For Reimbursement.

Relator continues to be unable to identify a false statement connected to a claim for payment—whether that statement be express or implied. Mot. at 16–17. Relator at times appears to concede

[8] Relator also alludes to a brand new theory of liability—that the "misrepresentations and omissions constituted 'false records or statements material to a false or fraudulent claim' for Zytiga"—not raised in his Complaint. *Compare* Opp. at 9, *with* AC ¶ 119 ("Through the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment."). But Relator abandons this theory as soon as he articulates it, arguing instead that he adequately pled "a False Statement or Fraudulent Course of Conduct That Caused the Government to Pay Money," Opp. at 14, or "False Statements in Connection With Zytiga's Listing on the Federal Supply Schedule," *id.* at 15.

this point, *e.g.*, Opp. at 14 (arguing that FCA liability does not require "a specific misrepresentation in the actual claim itself"), while elsewhere suggesting that the mere inclusion of the federally approved price on the claim for payment (which Relator has not otherwise pleaded with any generality, let alone particularity) is somehow fraudulent, *id.* at 9–10. However, there is nothing "false" about the approved price for Zytiga.

As an initial matter, Relator does not claim that the price is *factually* false. Mot. at 16. Instead, he represents only that "the claims for payment specifically included prices Defendants represented were fair and reasonable." Opp. at 10. By this formulation, Relator thus attempts to skate past whether the purported misstatement was actually in the claim for payment, and avoids specifying where the purported misstatement was actually made. Unsurprisingly, as where Relator fails to plead any details about any particular claim for payment themselves, he necessarily cannot plead any express representations contained therein. Mot. at 13–14.

That leaves an impliedly "false" price. But this misconstrues the nature of an implied misrepresentation—a specific representation *concerning a good or service* that is made a "misleading half-truth[]" due to the omission of some material, regulatory non-compliance—because Relator cannot connect the claimed regulatory non-compliance with the claim itself. *Id.* at 17 (quoting *Escobar*, 136 S. Ct. at 1999). Relator invokes *Escobar* and *Campie* for the sufficiency of his allegations. His reliance is misplaced for several reasons.

First, in *Escobar* and *Campie*, the claims for payment themselves contained "misleading half-truths" as to the goods or services being provided.[9] In *Escobar*, the claim contained billing codes that necessarily misrepresented the qualifications of treatment providers, in violation of state regulations governing licensing and supervision requirements. 136 S. Ct. at 1997. The codes had concrete meanings, and defendants told a "half-truth" when they did not disclose employees' non-compliance. *See id.* at 2000. In *Campie*, too, the claims for payment misrepresented the nature of the goods provided: the defendant represented that its products had been manufactured in registered facilities that met FDA standards, when they had not been. 862 F.3d at 895–96 (citing 21 U.S.C. § 355(d)–(e);

[9] "[H]alf-truths" are "representations that state the truth only so far as it goes, while omitting critical qualifying information." *Escobar*, 136 S. Ct. at 2000.

21 C.F.R. §§ 210–11). The claims requested payment for "FDA approved" drugs, but the drugs allegedly fell outside the scope of FDA's approval. *Id.* at 902–03.

Here, by contrast, Relator fails to plead that the alleged underlying conduct rendered the description of Zytiga misleading or caused any other "half-truths" to be made *in* the claim for payment. Both the drug and the price accurately reflected what was contracted for, and Relator does not allege that the pricing calculation was inaccurate. *See* Mot. at 18–19. Moreover, every claim for payment could not impliedly misrepresent Zytiga's price as "fair and reasonable," because, as explained in Defendants' Motion, a price is deemed "fair and reasonable" by the federal contracting officer, *not* the manufacturer. *Id.* By submitting a claim for payment at a particular price, a claimant is at most representing the drug is listed for payment or reimbursement on the FSS at that price. There is nothing "false" about that representation—impliedly or otherwise.

Second, in *Escobar* and *Campie*, there was a direct connection between the regulatory fraud at issue and the false claim for payment—the "misleading half-truths" were directly derived from the underlying regulatory fraud. *Campie* itself recognized that the key issue is "the connection between the regulatory omissions and the claim for payment." 862 F.3d at 903 (citing *U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 492 (3d Cir. 2017)).[10] That does not mean, as Relator would have it, that any allegedly false statement made in the course of any regulatory proceeding renders false any future claim for payment that can be remotely tied to it. Such a theory would effectively erase the crux of FCA liability—the actual false claim. Relator's theory contains no comparably direct "connection between the regulatory omissions and the claim for payment." *Campie*, 862 F.3d at 903.

2. Relator Fails To Plead A False Statement In Connection With Federal Drug Pricing.

Because Relator cannot allege that the claim for payment itself is false or otherwise misleading, he is forced to seek a hook elsewhere in the claims process, which he attempts to do by claiming Defendants "provided explicit and implied representations to the government that the price

[10] Because the relevant authorities expressly contemplate that the claimed regulatory violation will have a sufficient nexus to the alleged "half-truth" (*i.e.*, the falsity of the claim), this query is properly entertained as an element of the claim on a motion to dismiss, contrary to what Relator may contend. Opp. at 14–15.

of Zytiga was 'fair and reasonable,'" Opp. at 8. Notably, Relator nowhere pleads a single affirmative representation by any Defendant that its prices were "fair and reasonable." And, even if he could, Relator attempts to pour into "fair and reasonable" meaning that is simply not there.

To the contrary, the Opposition ignores how "fair and reasonable" prices are established: whether a price is "fair and reasonable" is a determination made *by the government* based on a prescribed set of required pricing data. Mot. at 18–19. Relator does not contend that Defendants submitted inaccurate pricing data about their commercial sales, or that the price the contracting officer found to be "fair and reasonable" lacked the requisite algorithmic relationship to Defendants' commercial pricing. *See* 48 C.F.R. § 8.404(d); RJN, Ex. H at CP-8, 53. In short, Relator identifies no statute, regulation, or case law to support his contention that "fair and reasonable" constitutes an express and falsifiable representation or imposes some sort of normative obligation on manufacturers beyond submitting the required pricing information. There is no express falsity.

Similarly, Relator's winding tour through the Code of Federal Regulations merely confirms the contrast between his attenuated allegations and those at issue in *Campie* (putting aside that the alleged implied misrepresentations at issue in *Campie* existed on the claim itself). Relator, for instance, points to general Federal Acquisition Regulation ("FAR") terms concerning the role "adequate price competition" might play in setting prices for government acquisition and procurement, Opp. at 16 (citing 48 C.F.R. § 15.402(a)(2)(ii)), but that regulation does not even apply to "orders placed against Federal Supply Schedules contracts." 48 C.F.R. § 8.404(a). Never mind that Relator nowhere shows that the validity of a patent is in any way related to or taken into consideration for the fair-and-reasonable price determination, as he must to establish a theory of falsity based on patent validity. The Complaint does not allege a valid implied misrepresentation theory.

For these same reasons, Relator's attempt in his Opposition to manufacture an unpled "promissory fraud" theory is also unavailing. In the Ninth Circuit, implied and promissory theories share "very similar" elements, *Campie*, 862 F.3d at 902, and a viable FCA claim based on promissory fraud is rare, *see U.S. ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996). Because Relator has not pled that Defendants ever made a representation or certification that its prices were "fair and

reasonable," they could not have induced a contract on that basis. Additionally, because the *government's* "fair and reasonable" determination was made using commercial pricing information—which Relator has not challenged as inaccurate or false—the determination itself could not have been fraudulently obtained. Finally, any alleged fraud on the USPTO is far too attenuated to give rise to FCA liability under this theory, as well. Even the government "does not believe that a claim is necessarily 'fraudulent' simply because some antecedent fraud was the 'but for' cause of the claim being submitted. Rather, at some point the causal chain can become so attenuated that the subsequent claim for payment no longer retains the 'taint' of the defendant's initial fraud." Brief for the United States of America as Amicus Curiae Supporting Appellants at 27, *Campie*, 862 F.3d 890 (No. 15-16380), 2016 WL 211750.

3. Relator Fails To Plead Inequitable Conduct Before the USPTO.

Relator's Complaint is flawed to its core. Each of his varied theories of liability relies at bottom on a claim of inequitable conduct before the USPTO; therefore, Relator must adequately plead the elements of that claim. *See* Mot. at 20–22. That is, Relator must plead (i) specific misstatements or omissions, that (ii) were "but-for" material to the issuance of the patent, and (iii) made with intent to deceive the patent examiner. *See id.* at 20–21 (citing cases). Each of these allegations must conform to Rule 9(b), as applied by the Federal Circuit. Relator's Complaint fails to do so.

Relator offers no substantive response, and instead seeks to excuse himself from the Federal Circuit's standards by arguing that he need not allege an inequitable conduct claim and that his claim is governed by common law fraud instead. Opp. at 18. But Relator's argument collapses under its own logic. The central refrain in Relator's Complaint is that Defendants' allegedly fraudulent statements or omissions before the USPTO were in direct contravention of the statutory "duty of candor and good faith." *See, e.g.*, AC ¶¶ 53, 64 (quoting 37 C.F.R. § 1.56). That duty is the basis for the inequitable conduct standard. *See Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1186 (Fed. Cir. 2006) ("Inequitable conduct occurs when a patentee breaches his or her duty to the PTO of 'candor, good faith, and honesty.'" (quoting *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1342 (Fed. Cir. 2005))). Relator cannot bring a claim premised on a breach of a regulatory duty on individuals appearing before the USPTO, and yet argue that he need not meet the standards

required to plead a breach of that duty. *Compare* Opp. at 3–4 *with id.* at 17–18. Relator's illogic could result in FCA liability founded on fraud before the USPTO in securing a patent based on allegations insufficient to invalidate the patent—a self-evidently absurd proposition that would undercut the protections the Federal Circuit has erected to the patent law system.

Relator also points to *Escobar* to suggest that common law theories of fraud apply, *id.* at 18, but he misrepresents the case. *Escobar* looked to the common law to explore the meaning of fraud within the context of a "claim for payment" under the FCA. 136 S. Ct. at 1999. Nowhere did the Supreme Court suggest that common law standards would displace a preexisting regulatory framework governing conduct that forms the basis of a *qui tam* action.[11] And, courts have imported the Federal Circuit's inequitable conduct standard into other statutory constructs, such as the Sherman Act. *See Ritz Camera & Image, LLC v. SanDisk Corp.*, 772 F. Supp. 2d 1100, 1106 (N.D. Cal. 2011) ("The first barrier ... to clear is the requirement that the patent be obtained through actual fraud upon the PTO. This question is governed by Federal Circuit law." (quoting *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1346 (Fed. Cir. 2007)).

Lastly, Relator also makes a weak-hearted claim that he has sufficiently met the inequitable conduct standard. He has not. Relator fails altogether to address many of Defendants' points, including: (i) that many of the purported "misstatements" are not actionable as fraud, *see, e.g.*, Mot. at 22 (citing AC ¶ 80(a)); (ii) that other "misstatements" are entirely speculative, *id.* (citing AC ¶ 80(b), (f)); and (iii) that the undisputed USPTO record makes clear the '213 Patent was placed before the patent examiner, directly contradicting Relator's allegations that the examiner was unaware of the patent, *see id.* (citing RJN, Ex. I at 7, 10).

What Relator does address is no better. For the most part, Relator tries to salvage an allegation about the "who" of the alleged fraud by naming two individuals as charged with the duty of candor. Opp. at 19. But, these people appear nowhere in the Complaint. Even if these allegations through briefing were proper—which they are not—they do not meet the pleading standards articulated in *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329 (Fed. Cir. 2009). There is simply no

[11] At no point does Relator explain *what* a common law theory of fraud would require him to plead, and ultimately prove, as to Defendants' purported conduct before the USPTO.

factual allegation to support the contention that the '438 Patent inventor, or the patent attorney who made the June 4 submission, *deliberately* withheld relevant facts. Opp. at 12. Nor does the Complaint allege that any of the individual purported misstatements or omissions were "but-for" material to the patent examiner's decision to issue the '438 Patent. Mot. at 20–21. Neither the Complaint nor the Opposition provide any facts to support the alleged misconduct and rely on conclusory allegations that two alleged omissions were material. *See* Opp. at 19 (citing AC ¶¶ 78–79). Relator's *ipse dixit* is entitled to no weight. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

In sum, Relator can neither escape nor meet the heightened pleading standard for inequitable conduct. Because Relator's entire theory hinges upon this specific claim of fraud, this failure is independently fatal to his case.

C. Relator Fails to Allege Materiality Under *Escobar*.

As demonstrated in the Motion, Relator fails to plead that conduct before the USPTO is material to either the government's decision to list Zytiga on the FSS or to pay any claim. Mot. at 23–25. The Opposition adds nothing to show that Relator meets *Escobar*'s "demanding" materiality standard. *Id.*

First, the Opposition improperly relies on a dressed-up legal conclusion, entitled to no deference, that anti-competitive conduct would necessarily be dispositive to a contracting officer's fair-and-reasonable determination. *E.g.*, Opp. at 10 ("[E]nsuring that the price of medicine is fair and reasonable—and not artificially inflated through the unlawful exclusion of competitors—is central to the regulatory framework governing payments under government health programs."). That is wrong. Moreover, Relator misreads *Escobar*, which makes clear that statutory, regulatory, and contractual requirements declared to be conditions of payment are not automatically material, as Relator suggests. *Escobar*, 136 S. Ct. at 2001; *Cf. U.S. ex rel. Rose v. Stephens Inst.*, 909 F.3d 1012, 1020 (9th Cir. 2018) ("After *Escobar*, it is clear that noncompliance [with the applicable regulation] is not material per se."). At bottom, Relator asks the Court to take his word for it, without factual support, that the various government health programs would refuse payment for Zytiga if they were aware of his allegations of misconduct before the USPTO. *Cf. U.S. ex rel. Durkin v. Cty. of San Diego*, 300 F. Supp. 3d 1107, 1127 (S.D. Cal. 2018) (finding a lack of materiality where allegations were "largely

conclusory"). This falls well short of the particularized pleading requirements necessary to meet the "rigorous" materiality standard set forth by *Escobar*. *See* 136 S. Ct. at 2003 n.4. And, of course, after the government received Relator's allegations, it continued to pay the FSS list price for Zytiga, which weighs heavily against materiality.

D. Relator Has Not Alleged That J&J Intended To Submit False Claims.

Lastly, Relator fails to plead scienter. While courts must "rigorous[ly]" examine allegations of scienter, *Rose*, 909 F.3d at 1024, Relator does nothing more than mouth the rote elements, Mot. at 25. In his Opposition, Relator packs a single paragraph with a smorgasbord of assertions, none of which has anything to do with scienter. He claims that Defendants' Motion to Transfer somehow conceded the issue by noting the location of various J&J employees and entities alleged to have made various representations. Opp. at 13. But that is not scienter, and the Motion to Transfer did not concern *certification* or *representation* of prices. Relator also notes that the conduct of individual agents may be imputed to their corporate principals. *Id.* But, that is of little help as he fails to plead any underlying individual's scienter. Moreover, Relator's invocation of statements made to the Patent Office, for example, conflates the scienter required to prove inequitable conduct before the USPTO, with the separate scienter required to prove the knowing submission of a false claim for payment. In the final analysis, Relator points to nothing to prove that J&J submitted claims for payment knowing them to be false or with reckless disregard for their falsity.

CONCLUSION

For the foregoing reasons, as well as those stated in Defendants' Motion to Dismiss, the Court should dismiss Relator's complaint with prejudice.

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